

**1033 Left Main PTCA: Closure Devices**

Monday, March 30, 1998, Noon-2:00 p.m.  
Georgia World Congress Center, West Exhibit Hall Level  
Presentation Hour: Noon-1:00 p.m.

**1033-101 Initial and Long-term Results of Elective Angioplasty in Unprotected Left Main Coronary Artery**

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Unprotected left main coronary artery (ULMCA) angioplasty has been considered to be contraindicated. Recent studies suggest that new devices improved its results with relatively small number of patients and short-term follow-up. We analyzed our data of ULMCA angioplasty and evaluated its feasibility and effectiveness.

**Methods:** Between 2/86 to 8/97, consecutive 145 procedures in 94 patients with ULMCA stenosis were performed electively. There were 82% male and 40% restenosis cases. Final treatments were directional atherectomy (DCA) (50%), balloon angioplasty (41%), and stents (8%). There were 29% three vessel diseases, 19% heart failure and/or unstable angina, 32% age  $\geq 75$ , 65% prior MI, 6% prior CABG, and 22% EF  $< 35\%$  cases. Follow-up angiography was scheduled at 1 day and at 3, 6, and 12 months after angioplasty.

**Results:** 1) Initial results: ULMCA stenoses of 140 cases (97%) were improved to  $\leq 50\%$ . There were 2 (1.4%) cardiac death, 3 (2.1%) non-cardiac death, 2 (1.4%) QMI, 7 (4.8%) non-QMI, 10 (6.9%) repeat angioplasty, and 0 (0%) CABG. 2) Restenosis rate: Restenosis rate was 35.2% within 3 months, and 47.0% within 1 year. The restenosis rate of DCA was 26.3% and lower than that of balloon angioplasty (63.2%,  $p < 0.0005$ ) and that of stents (44.4%,  $p = NS$ ). 3) Long-term results of 94pts: Mean follow-up period was 2.6 years. Three-year survival rate was 80.6%, and 3-year cardiac survival rate was 90.0%.

**Conclusions:** ULMCA angioplasty is feasible and effective under scheduled angiographic follow-up. DCA is promising procedure for ULMCA stenosis because of its lower restenosis rate.

**1033-102 Directional Atherectomy or Stenting for Unprotected Left Main Coronary Stenoses - The ULTIMA Group Experience**

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Encouraging results from modest series of patients (pts) have been reported for both directional atherectomy (DCA) and stents (S) used to treat pts with unprotected left main stenoses (ULMS). To compare their relative benefit we queried a registry of 229 non acute MI consecutively treated ULMS pts from 25 centers treated since 1/94. Follow-up angio was 75% complete at  $6 \pm 3$  mos.

	DCA (n = 46)	Stent (n = 148)
Age (yrs)	68 $\pm$ 10	64 $\pm$ 14
LVEF (%)	54 $\pm$ 14	54 $\pm$ 15
Rest or progressive angina (%)	30.4	40.1
Moderate-severe calcium (%)	21.7	28.0
Distal ULMS (%)	69.6	47.7
Bypass status-high risk (%)	21.7	28.6
Inoperable (%)	2.2	15.0
In hospital death, MI, CABG (%)	4.3	5.5
Restenosis (%)	21.7	27.5
6 month death, MI, revasc (%)	23.0	32.6

After adjusting for these and other variables in Cox analysis, there was no difference between DCA and stents for 6 month outcome ( $p = 0.26$ ). Both appear promising for treatment of ULMS, but need to be formally compared with CABG.

**1033-103 Mechanical Approach in the Recanalization of Total Coronary Occlusions: A Consecutive Series of 322 Lesions**

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From January 1996 to July 1997 interventions on 322 consecutive total coronary occlusions (301 patients) were attempted at our institution according to

a standardized protocol. This protocol consisted in the use of first a floppy, hydrophilic coated wire (Choice PT-Somed) followed in case of no success by a 0.014 or 0.010 inch standard wire (Athlete-Asahi, In-torque-ACS). Furthermore in all cases low profile over-the-wire balloons (Ranger-Somed, Predator-Cardis) were used to support the wire.

The age of occlusion was  $\leq 4$  weeks in 5%,  $> 4$  weeks and  $\leq 3$  months in 28%,  $> 3$  months in 35% and undetermined in 32% of cases. Bilateral injections in case of presence of retrograde collateral filling were used in 38% of cases. The overall mechanical crossing success was 73%. The floppy wire successfully crossed the occlusion in 44% of cases, a stiff wire in 21% and the combined use of a floppy and a stiff wire, both determinant for the progression in the occlusion in 8%. After mechanical crossing failure a laser wire was used in 7 occlusions (2%) with a 43% success rate. Procedural success with re-established TIMI 3 antegrade flow was achieved in 62% of all lesions. Stents were used in 72%, rotational atherectomy in 12% and directional atherectomy in 10% and laser atherectomy in 4% of cases. Complications were: 1 death (0.3%), 5 urgent CABG (2%), 3 perforations with tamponade (1%), 2 Q wave infarction (0.6%), 5 non Q wave infarction (2%) and 25 cases of local contrast staining (8%). Two-hundred-fifty lesions were treated 6 months before present time and therefore eligible for angiographic follow up which was obtained in 60%. The  $\geq 50\%$  diameter stenosis rate was 40%.

**Conclusions:** The "old" mechanical recanalization technique using "new" wires and balloons has a high success and low complication rate. Results of emerging new recanalization devices need to be compared with present data.

**1033-104 Immediate Post PTCA Percutaneous Suture of Femoral Arteries With the Perclose Device: Results of High Volume Users**

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**Background:** The reported results of percutaneous arterial sutures using Perclose devices (Techstar/Prostar) are contradictory and most reported series include the learning curve of the users.

**Methods:** To overcome these drawbacks, a prospective single center study was carried out with 2 physicians whose individual experience was  $> 250$  arterial sutures immediately after PTCA.

**Results:** 104 consecutive pts (77.8% male, mean age 60.9 yrs) were treated. The device used was 6F 2 needles (80 pts), 8F 2 needles (20 pts) and 8F 4 needles (4 pts). Mean ACT at the time of closure was 426.3 s (188 to 1500 s). Mean procedural time was 3.19 min (1.23 to 10.30 min). The suture was immediately effective in 93 pts (89.4%) who did not require compressive bandage, leg immobilization or bed confinement (Group 1). In the remaining cases bleeding was treated with Femostop, applied  $< 1$  hr. in 8 cases (Group 2). The pts were then managed as Group 1 (no compression, no immobilization). Femostop was applied for 1 to 3 hrs. in 3 cases followed by compressive bandage and 12-hr leg immobilization (Group 3). At discharge, no cases of hematoma were observed in Group 1 and 2 (97%). In Group 3, 1 pt had surgery for a false aneurysm and 1 pt had an uncomplicated small hematoma. All pts were followed by phone at day 15. No late complications occurred.

**Conclusion:** After a prolonged learning curve period, closure of femoral arteries with Perclose device is fast, effective and improves dramatically patient comfort in the post procedural period. The potential decrease in access site complication rate together with shorter hospital stay may balance the cost of the device.

**1033-105 A Small Plug for a big Hole: Safety and Efficacy of Eight French AngioSeal™ for Closure of Nine French Arteriotomy Site Immediately Following Percutaneous Coronary Interventions**

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In selected percutaneous coronary intervention procedures, 9 French (Fr) guide catheters are used for stronger support, larger lumen and better visu-

	9 Fr (n = 32)	8 Fr (N = 55)	P value
Age (year)	63 $\pm$ 12	67 $\pm$ 13	NS
ACT* (sec)	261 $\pm$ 84	261 $\pm$ 80	NS
TTH† (sec)	233 $\pm$ 742	238 $\pm$ 1060	NS
Male	63%	72%	NS
Hematoma $> 5$ cm	0%	2%	NS
Transfusion	0%	0%	NS
Vascular Repair	0%	0%	NS

(\* = activated clotting time at sheath removal, † = Time to Hemostasis)